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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HENDRICKS, KEITH D

ART UNIT

PAPER NUMBER

1761

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9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/921,492

Applicant(s)

JOHANSEN, LISBETH HOJ

Examiner

Keith Hendricks

Art Unit

1761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 and 5-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of proteases as the enzyme, or L-cysteine, metabisulphites and glutathione as the reducing agents, does not reasonably provide enablement for the broadly-claimed use of any "enzyme" or "reducing agent." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Initially, it is noted that proteases are the main class of enzymes known to "modify" proteins. Thus, applicants' claims are not commensurate in scope with the enablement provided in the specification, as well as that known in the art at the time the invention was made. Regardless, applicant has shown no effective reasoning or evidence behind the use of any other type of enzyme, such that the desired and disclosed results could be repeated by one skilled in the art. It would require an inordinate amount of experimentation for one skilled in the art to randomly obtain, test and screen the effects of the hundreds of other types of enzymes known in the art, absent some such specific guidance toward the effect and goal of another class of enzymes upon masa corn production. Similarly, the term "reducing agent" is, in many ways, even broader than the term "enzyme", because this encompasses any class of compounds, and any specific compound which is, logically, not an oxidizing agent, or neutral. Applicant has provided no general or specific guidance toward the selection of which compounds of this extremely broad class, would function within the claimed invention, and more importantly, function properly as claimed and disclosed, without producing a detrimental, undesired food product. Other than the specific compounds mentioned above (proteases, L-cysteine, metabisulphites and glutathione), no other types of enzymes or reducing agents even appear to be disclosed, and thus the positive effects of the hundreds of other classes of compounds, would require an undue amount of experimentation for one skilled in the art to determine. The disclosed showing of the small set of compounds is not predictive of a broader range of compounds which only have a remote common functionality by name alone.

Art Unit: 1761

A number of factors must be considered in assessing the enablement of an invention, including the following: the breadth of the claims, the amount of experimentation necessary, the guidance provided in the specification, working examples provided, predictability, and the state of the art. See *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

NOTE: *This application is a direct copy of a foreign document. Applicants' representative is strongly encouraged to review the application, especially the claims, to comply with accepted U.S. Patent structure and language. The claims are generally narrative and indefinite, failing to conform with current U.S. practice, and are replete with grammatical and idiomatic errors. The rejections under 35 USC 112 2nd paragraph below are an attempt to call attention to these occurrences, yet may not be comprehensive.*

The term "modified" is indefinite, as the metes and bounds of this term are unclear, and are not set forth within the claims or specification. The 'definition' provided at page 4 of the specification simply repeats the phrase as used within the claim, and thus does not provide any clear distinction of what is accomplished by the claimed invention. See also page 6 of the specification. While claims in an application, in general, may be entitled to broadly encompass a large number of possible "modifications", they must still be definite within the boundaries of this statute, such that one skilled in the art would be apprised of what is encompassed by the claim. One skilled in the art would not be apprised of such scope, as the term "modified" does not refer to any particular type(s) of alteration, either broadly or specifically.

Claims 2 and 4 are indefinite for the recitation of the grouping of optional items. It is unclear if this is an open or closed set; the use of "selected from... and", should be "selected from the group consisting of... and", in order to indicate the closed set.

In amended claim 2, "soft totrilla" is misspelled.

Claim 2 is indefinite, as it is unclear as to what is encompassed by "derivatives and mixtures thereof" of the recited elements, namely tortillas, chips, taco shells, and tamales. It is unclear as to how "derivatives" of these food items may be made, and what such "derivatives" would encompass. Further, it is unclear as to how one skilled in the art is to make a "mixture", i.e. combination, of the food items

Art Unit: 1761

provided. Once the individual item is made, it is encompassed by the claim, whether eventually combined with other items or not. It does not appear that the process of claim 1 may result in a "mixture thereof."

Claim 4 is indefinite for the recitation of "inactivated yeast extract (glutathione)." These are not the same items, and thus it is unclear whether the limitation of "(glutathione)", following the phrase "inactivated yeast extract", is part of the claimed invention. See MPEP § 2173.05(d).

In claim 4, the term "cystein" should be spelled "cysteine", the accepted U.S. spelling.

In amended claim 4, the term "mistures" should be "mixtures."

Claims 5 and 6 are indefinite from the recited language of "wherein the masa foodstuff further comprises...", as it is unclear at what point the *process* of the claims further incorporates carrageenan or guar. It is unclear whether these compounds are added prior to, or during, steps (i), or (ii), or after step (ii). The point of addition may or may not be expected to influence the process and resulting product; this is unclear from the claims.

Unless applicants are aware of a difference in the compounds, the term "guar", in claim 6, is suggested to be amended to indicate "guar gum", to more clearly set forth the metes and bounds of the claims. See line 21 of page 7 of the specification.

Claim 7 is indefinite for the phrase "obtained or obtainable". Initially, applicants' intent with regard to the use of both of these terms, is unclear. It is further noted that the term "obtainable" would not be expected to remove the claim from a prior art masa foodstuff, i.e., one that is "obtainable" from the claimed process, or any other.

Claim 8 is indefinite for the recitation of "...comprising a modified protein wherein the unmodified protein is native to corn." Initially, the necessity of this claim is unclear, as nixtamalized masa inherently contains "modified" proteins, and cooked masa foodstuffs also contain "modified" proteins, in that they are denatured upon cooking. This further illustrates the indefiniteness of the term "modified", as addressed above. Secondly, the phrase "the unmodified protein" lacks a clear antecedent basis within the claim. It is further unclear if this corresponds to the original protein prior to modification in the masa product. Finally, the phrase "the corn" also lacks a clear antecedent basis within the claims.

Claim 9 is indefinite for the phrase "improve the interaction of a protein". The term "improve" is a relative term, which is not defined by the claim. The specification does not provide a standard for

Art Unit: 1761

ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Further, the type of "interaction" of the protein is unclear, and with what component the protein is to "interact."

Claims 10-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to point out what is included or excluded by the claim language. These claims are omnibus type claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9-10 and 12 provide for the use of a reducing agent, or simply any "process as substantially described" in the examples; but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite under 35 U.S.C. 112 where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 9-10 and 12 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 7-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Gimmler et al. (US PAT 5,652,010).

Art Unit: 1761

Gimmler et al. disclose the preparation of masa corn by nixtamalization (see col. 3, "summary of the invention"). The corn material is treated with proteases during the steeping step, to reduce viscosity of the material, prior to cooking the corn in alkaline water (nixtamalization). See example 1.

It is noted that claim 4 does not necessarily further limit the invention of claim 1, in that it does not require that the masa and/or corn be contacted with the reducing agent. Claim 4 simply provides a further selection of the choices within claim 1, and still may be satisfied by a reference meeting the limitation of "or an enzyme", and thus the reference still anticipates the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gimmler et al., in view of Jensen et al. (WO 96/39865).

Jensen et al. disclose the use of a fat-free filler additional compound for use in the production of masa corn flour products, such as corn chips. Pages 4-5 discuss the additives, and includes both carrageenans and guar gum. The use of additional known components within a known recipe, to advantageously utilize their respective known contributive properties, would not have involved an inventive step. Thus, the inclusion of carrageenan or guar gum within the instantly-claimed tortilla-making process, would have been an obvious step for one of ordinary skill in the art to perform, given the positive teachings provided by the reference, and the state of the art at the time the invention was made. Further attention is invited to *In re Levin*, 84 USPQ 232 and the cases cited therein, which are considered in point in fact situation of the instant case. At page 234, the Court stated as follows:

This court has taken the position that new recipes or formulas for cooking food which involve the addition or elimination of common ingredients, or for treating them in ways which differ from the former practice, do not amount to invention, merely because it is not disclosed that, in the constantly developing art of preparing food, no one else ever did the particular thing upon which the applicant asserts his right to a patent. In all such cases, there is nothing patentable unless the applicant by a proper showing further establishes a coaction or cooperative relationship between the selected ingredients which produces a new, unexpected and useful function. In *re Benjamin*

Art Unit: 1761

D. White, 17 C.C.P.A. (Patents) 956, 39 F.2d 974, 5 USPQ 267; In re Mason et al., 33 C.C.P.A. (Patents) 1144, 156 F.2d 189, 70 USPQ 221.

Note that any such "coaction or cooperative relationship" must be commensurate in scope with the limitations of the claims to which it pertains.


Conclusion

The limitations of claim 4 (to the use of L-cysteine, metabisulphites and glutathione) would be allowable, if the claim was amended to incorporate the features of independent claim 1, and upon the claim(s) positively reciting the use of such compounds.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703) 308-2959. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (703) 308-3959. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9565 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


KEITH HENDRICKS
PRIMARY EXAMINER